

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC. PELVIC MESH REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
ETHICON WAVE 4 CASES LISTED IN DEFENDANTS' EXHIBIT A	

**PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO
EXCLUDE THE OPINIONS AND TESTIMONY OF
PROF. DR. MED. UWE KLINGE**

Plaintiffs submit their Response in Opposition to Defendants' Motion to Limit the Testimony of Prof. Dr. Med. Uwe Klinge. For the reasons contained herein, Plaintiffs respectfully request that the Court deny Defendants' motion in its entirety.

I. Introduction

For the *sixth* time, Ethicon comes before this Court, seeking to preclude the same expert, based on the same opinions. This motion is nothing more than a weakly-disguised motion for reconsideration that fails to present any truly new arguments or information not available on the multiple prior motions, and should be rejected out of hand. The instant motion revisits two of Dr. Klinge's opinions in particular yet again – safer alternative design and fraying/particle loss. Twice before this Court has found Dr. Klinge's opinions regarding PVDF as an alternative to polypropylene reliable, denying Ethicon's motions on this issue. *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, 2014 WL 186782 (S.D. W. Va. Jan. 15, 2014); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 (S.D. W. Va. Aug. 24, 2016). And in three previous rulings, this Court has denied Ethicon's motions to exclude Dr. Klinge's opinions regarding fraying and particle loss. *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 (S.D. W. Va. Nov. 20, 2014); *In re Ethicon, Inc., Pelvic Repair Sys.*

Prods. Liability Litig., No. 2:12-MD-02327, 2014 WL 186782 (S.D. W. Va. Jan. 15, 2014), *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 (S.D. W. Va. Aug. 24, 2016).

Essentially, the only substantive addition to this Wave 4 brief that was not included in Ethicon's prior briefing is a short section in the beginning—based upon the Fourth Circuit's recent holding in *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. Feb. 1, 2017)—arguing that Dr. Klinge's opinions on safer alternative design opinions should be excluded.¹ Def.'s Brf. at 3-4. But as discussed below, *Nease* did not change the law of this Circuit; it is factually and legally inapposite; and it requires no departure from—or reconsideration of—this Court's prior *Daubert* opinions.

Recognizing that the Court has stated in recent orders that it does not intend to rely wholesale upon previous rulings in arriving at its opinions in response to more recent filings, plaintiffs herein will respond to each of Ethicon's arguments in its current briefing.² Ethicon's attempts to exclude Dr. Klinge's testimony on alternative design and fraying/particle loss should be rejected again as their "new" arguments are nothing more than a rephrasing of their prior rejected arguments, and do not justify altering the Court's prior rulings.

II. Dr. Klinge's Background and Credentials

Dr. Klinge is a unique expert in this litigation in the fields of biomaterial science and abdominal surgery – in that he was one of the original scientists using and studying the safer alternative designs of surgical meshes from the mid-1990's up to the present, including 10 years as a consultant to Ethicon during which he performed hundreds of studies on the Prolene mesh used by Ethicon in nearly all of its SUI and POP products. He has studied, tested, and been published

¹ Ethicon also includes a few citations to *Nease* elsewhere in its brief.

² Plaintiffs will not address Ethicon's arguments in Section III of its brief seeking exclusion of opinions concerning Ethicon's knowledge, state of mind and corporate conduct as plaintiffs do not intend to elicit such testimony in line with this Court's "Recurring Issues" rulings in recent orders. As such, this is a moot point.

numerous times in the peer-reviewed literature on the design properties of the Prolene mesh used in Ethicon's SUI TVT meshes and the Gynemesh PS mesh used in Ethicon's POP meshes, Prolift and Prolift+M. Despite Dr. Klinge's exceptional and unique qualifications, including his extensive experience as a trusted consultant for Ethicon and one of the researchers at the forefront of safer alternative mesh design and mesh complications, Ethicon continues to claim that the man they turned to for a decade of mesh research cannot meet the *Daubert* standards that this Court has repeatedly found to be satisfied.

Although Dr. Klinge's qualifications are well known to the Court, they bear repeating in response to the instant briefing. As described in the attached exhibits, Dr. Klinge has been an internationally recognized expert in biomaterials research and the safe design of surgical meshes for more than 20 years. (Klinge Curriculum Vitae, attached as Exhibit 1; Klinge Report, attached as Exhibit 2, at 1). Dr. Klinge and his collaborators were the innovators of the mesh-related concepts of fibrotic bridging, scar plate formation, effective porosity and lightweight/large pore mesh – concepts that Ethicon came to accept and use. (Exhibit 2, at 2-3). Dr. Klinge and his fellow surgeons and scientists were also among the first to study the alternative material, PVDF, as consultants to Ethicon. (Klinge *de bene esse* 11/10/14, incorporated as reference to Klinge report, at Exhibit C, 193:12-196:19, attached hereto as Exhibit 2; Klinge 2012 Gross report, incorporated as reference to Klinge report at Exhibit D, page 214, attached hereto as Exhibit 2). In fact, Ethicon sponsored (and provided the PVDF mesh for) a study where Dr. Klinge and his colleagues compared PVDF to Ethicon's Prolene mesh. (Conze, J., Junge, K., Weiss, C., Anurov, M., Oettinger, A., Klinge, E., Schumpelick, V. New Polymer for Intra-Abdominal Meshes – PVDF Copolymer. *Journal of Biomedical Materials Research Part B: Applies Biomaterials* 2006, attached as Exhibit 3; Klinge *de bene esse* 11/10/14, incorporated as reference to Klinge report, at Exhibit C, 195:5-196:2, attached hereto as Exhibit 2). He has authored or co-authored approximately 200

peer-reviewed publications, more than 100 of which are on the topic of surgical meshes. (Klinge Curriculum Vitae, attached as Exhibit 1, at 2-20; Klinge Report, attached as Exhibit 2, at 5).

Ethicon itself retained Dr. Klinge as a consultant from 1994 to 2004 and has relied upon his expertise regarding biocompatibility and tissue response to surgical meshes, as reflected by countless internal documents created and/or exchanged between Dr. Klinge and Ethicon. (Klinge Curriculum Vitae, attached as Exhibit 1, at 39; Klinge Report, attached as Exhibit 2, at 2-3; Klinge Dep. 11/14/2013, incorporated as reference to Klinge report, at Exhibit H, 95:18-96:16, attached hereto as Exhibit 2; Klinge Dep. 10/5/2015, incorporated as reference to Klinge report at Exhibit O, 34:17-35:6, attached hereto as Exhibit 2).

Dr. Klinge's work in developing the mesh that was ultimately patented and sold by Ethicon as "Vypro" resulted in defining the minimum distance necessary between pore fibers as 1000 microns (or 1 mm), to prevent the pores from filling with scar tissue and hardening the mesh. (Klinge Report, attached as Exhibit 2, at 3, 5-7, 12-14, 27; Klinge Dep. 11/14/2013, incorporated as reference to Klinge report, at Exhibit H, 147:20-149:19, attached hereto as Exhibit 2). In 2002, Dr. Klinge co-authored a groundbreaking publication regarding this pore size requirement titled: "Impact of polymer pore size on the interface scar formation in a rat model." J. Surg. Res. 2002 Apr; 103(2):208-14. (Klinge Curriculum Vitae, attached as Exhibit 1, at 5). As noted in that peer-reviewed journal article, the scientific work detailed therein was funded by Ethicon.

One year later, at Ethicon's invitation, Dr. Klinge presented at an Ethicon conference on "Light Mesh Theory and Science," which covered the benefits of light-weight, large-pore mesh, including lower risks to patients. (Klinge Dep. 11/14/2013, incorporated as reference to Klinge report, at Exhibit H, at 230:1-22, attached hereto as Exhibit 2). In 2005, he co-authored another groundbreaking publication on that subject – "The lightweight and large porous concept for hernia repair." Expert Rev. Med. Devices. 2005; 2(1). (Klinge Curriculum Vitae, attached as Exhibit 1, at

11). In 2007, Ethicon invited Dr. Klinge to give presentations regarding his experiences with textiles in surgery. (Klinge Dep. 11/14/2013, incorporated as reference to Klinge report, at Exhibit H, 195:21-196:11, attached hereto as Exhibit 2; “Pelvic Floor Mesh Forum,” attached as Exhibit 4; “Wissenschaftliche Grundlagen und klinische Evidenz von Netz-Implantaten,” attached as Exhibit 5; “Experimental investigations with alloplastic materials: Which properties are essential for use at the pelvic floor?” attached as Exhibit 6).

Finally, in addition to this Court finding Dr. Klinge capable and qualified to testify on the design and *in vivo* properties of mesh, as well as the human response to those properties, numerous other courts have found his testimony in both Prolift and TVT trials to be relevant, reliable, and admissible. As early as February 4, 2013, the Honorable Carol E. Higbee of the Superior Court of New Jersey, Atlantic County, ruled that Dr. Klinge was qualified as an expert in the fields of abdominal surgery, biomaterial science, tissue reaction and tissue engineering, and histopathology for surgical meshes in the human body. (2/4/13 Trial Transcript, *Gross, et al. v. Ethicon, Inc., et al.*, Superior Court of New Jersey, Atlantic County, Civil Division, No. ATL-L-6966-10, incorporated as reference to Klinge report at Exhibit F, 3405:3-11, attached hereto as Exhibit 2) and more recently, the Honorable Judge Mark Bernstein and the Honorable Judge Powell have similarly ruled that Dr. Klinge’s *de bene esse* testimony on both the Prolift and TVT devices were relevant, reliable and admissible. (*Hammons v. Ethicon, Inc., et al.* Court of Common Pleas Philadelphia County, May Term, 2013, No. 3913; *Carlino, et al. vs. Ethicon Women’s Health and Urology, A Division of Ethicon, Inc. et al.*, Court of Common Pleas Philadelphia County, June Term, 2013, No. 003470).

Ethicon retained Dr. Klinge as a mesh consultant for 10 years because he is a world leader in the study and research of mesh biocompatibility, tissue response, safer alternative design and the complications associated with polypropylene mesh in the human body. Ethicon’s internal

documents reflect that Ethicon continues to rely upon Dr. Klinge’s research and conclusions, which he formed, in substantial part, during his years as a consultant for Ethicon – not for purposes of litigation.

III. Law and Argument

A. Dr. Klinge’s Opinions on Alternative Designs to the Prolene Mesh in Ethicon’s TVT Line of Products

As it has previously done,³ Ethicon again challenges the reliability of Dr. Klinge’s expert testimony regarding alternative design features to that of Ethicon’s heavy weight, small pore Prolene mesh used in all of its TVT products. Ethicon’s arguments must again fail based on the same reasoning that this Court applied in the past to this issue.

1. The Fourth Circuit’s Opinion in *Nease* does not change the Court’s analysis

Really, the only substantive addition to Ethicon’s Wave 4 motion against Dr. Klinge is the inclusion of a discussion of the recent Fourth Circuit opinion from *Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017). However, *Nease* does not change this Court’s *Daubert* analysis in any meaningful way. Indeed, the very passages from *Nease* relied upon by Ethicon in relation to *Daubert* standards, including the court’s discussion of “testing,” are for the most part direct quotes taken from prior—sometimes decades-old—Fourth Circuit opinions. *See e.g.*, Def’s Brf. at 4 (*citing Nease* quoting *Oglesby v. Gen. Motors Corp.*, 290 F.3d 244, 249 (4th Cir. 1999)).

Ethicon fails to provide any discussion of how *Nease* serves to change this Court’s prior analysis of, or rulings on, Dr. Klinge’s opinions. After spending several paragraphs discussing the facts and holding in *Nease*, Ethicon simply states: “[i]n applying the teachings of *Nease* to Dr. Klinge’s opinions, it is clear that the Court should preclude Dr. Klinge from testifying about potential alternative designs for the same reasons.” Def.’s Brf. at 4. The only thing clear is that

³ Def’s Memo in Support of Motion to Limit Testimony of Dr. Klinge [Dkt. 1982, at pp. 3-6].

Dr. Klinge's prior experience and study of mesh alternatives such as Ultrapro and PVDF, along with his reliance on scientific literature, satisfies the requirements of *Daubert*. As the Fourth Circuit reiterated, an expert may support his or her opinions through "evidence such as test data⁴ or relevant literature in the field." *Nease*, 848 F.3d at 231 (emphasis added). Dr. Klinge has clearly done so.

Dr. Klinge's opinions on alternative designs for surgical mesh should be beyond reproach at this point. For example, Dr. Klinge was among the first to study the alternative material, PVDF, as a consultant to Ethicon. *Supra*, 4-5. In fact, Ethicon sponsored the study that Dr. Klinge and his colleagues conducted comparing PVDF to Ethicon's Prolene mesh. *Id.* And if that specific experience with (and study of) PVDF was not enough, Dr. Klinge also relies upon countless articles on surgical mesh—many of which he himself has authored or co-authored. *Id.* Similarly, Dr. Klinge relies on extensive literature in support of his opinion about the use Ultrapro—a lighter-weight, larger pore mesh—including a study directly comparing Ultrapro to other meshes: Okulu, E., et al, (2013), *Use of three types of synthetic mesh material in sling surgery. A prospective randomized clinical trial evaluating effectiveness and complications*, Scandinavian J. of Urology, 2013, 47:217-224.

The support Dr. Klinge has provided for his opinions makes *Nease* easily distinguishable. In *Nease*,⁵ the court premised its ruling on numerous deficiencies in plaintiff's expert's opinions and testimony that simply do not exist in this case. For example, plaintiff's expert in *Nease* primarily relied upon a Ford FMEA that did not even apply to the model year of the car (2001 Ford Ranger) at issue. *Nease*, 848 F.3d at 224-25, 226, 232. Moreover, he acknowledged that: (1)

⁴ In *Nease*, the court merely focused on plaintiff's expert's lack of testing of the purported defect because there was no other support provided. *Id.* at 231 ("Testing was of critical importance *in this case*....") (emphasis added).

⁵ *Nease* is also legally distinguishable because, in that case, the plaintiff argued that *Daubert* did not even apply to the expert's testimony—and the Fourth Circuit took issue with the district court's ruling for not properly considering the expert's testimony under *Daubert*. *Nease*, 848 F.3d at 230. That has never been an issue with this Court's rulings in this TVM litigation.

during his examination of the plaintiff's car, he did not observe the conditions he opined could result in the malfunction; (2) the part at issue in plaintiff's car operated correctly during his examination of it; and (3) he had never—in plaintiffs' car or any other car—observed the defective condition he claimed could exist. *Id.* at 225-226, 231-32. In fact, plaintiff's expert could not even distinguish a working part from a non-working part in videos shown to him during trial. *Id.* at 226. In *Nease*, unlike here, the plaintiff's expert's theories were completely hypothetical and without support. And as the Fourth Circuit concluded, he “used no ‘methodology’ for reaching his opinions....” *Id.* at 232. That is just not the case with Dr. Klinge's opinions.

Finally, the Court should not even decide this issue on a “general” Daubert motion, applicable to all Wave 4 plaintiffs, in the absence of a consideration of the state law to be applied in each plaintiff's case. As this Court is well aware, what is and isn't required with regard to “safer alternative design” differs by state. For example, in *Nease*, the court's decision turned on the requirements of West Virginia law. *Id.* at 222, 233-234. As such, the court must consider the nature of the requirements—if any—imposed by the applicable state law in order to rule on the admissibility of Dr. Klinge's safer alternative design opinions.

2. Ultrapro

As Ethicon aptly points out in its moving papers, one of Dr. Klinge's opinions regarding alternative mesh design features to that of Prolene is “a mesh product with less material and larger distance between the fibers.” Def.'s Brf. at 5. One example of a mesh that has significantly less material and a much larger distance between the fibers is a mesh in Ethicon's own inventory of meshes – namely, Ultrapro.⁶

Here, Ethicon attempts to limit Dr. Klinge's opinion that Ultrapro mesh is a safer alternative to Prolene mesh, largely on the basis that Dr. Klinge does not think that Ultrapro mesh

⁶ Ultrapro was sold by Ethicon for use in hernia applications as well as in pelvic organ prolapse applications, before being taken off the market (prolapse repair) in 2012.

is perfect. But Dr. Klinge is not required to establish that Ultrapro is a no-risk device in order to testify that it is safer than Prolene. *See General Motors Corp. v. Sanchez*, 997 S.W.2d 584, 588 (Tex. 1999) (noting that a proposed alternative design must only *reduce the risk* of injury). As Dr. Klinge explained in his recent deposition, Ultrapro's design is superior to Prolene's:

The Ultrapro in its present form, or with these huge pores with this material reduction, has of course advantages in comparison to the Prolene material in regard to the tissue response. There has been a Turkish study clearly showing that it can be used as an alternative... for treatment of stress urinary incontinence.

(Klinge 10/5/2015 deposition, incorporated as reference to Klinge report at Exhibit O, 91:7-17, attached hereto as Exhibit 2). The study Dr. Klinge refers to, and which is listed in his report's reliance materials, is Okulu, E., et al, (2013), *Use of three types of synthetic mesh material in sling surgery. A prospective randomized clinical trial evaluating effectiveness and complications*, Scandinavian J. of Urology, 2013, 47:217-224 (attached as Exhibit 7). The study concluded that "Ultrapro mesh can be used in sling surgery due to its higher success rates, and its lower vaginal and urethral extrusion and de novo urgency rates, which have also been shown in clinical studies." Thus, Ethicon's primary objection to Dr. Klinge's testimony on this subject—that "Dr. Klinge does not cite a single clinical study to prove the safety and efficacy of a mid-urethral sling using Ultrapro or a mesh similar to it"—is demonstrably false. Def.'s Brf. at 5.

Further, in his report, Dr. Klinge spends pages and pages explaining the basis for his opinion (and the opinion of multiple Ethicon scientists) that lighter-weight, larger-pore mesh like Ultrapro is safer than Prolene. (Klinge report attached as Exhibit 2, at 9-15, 27-28) (detailing, with citation to published articles, Ethicon documents, and deposition testimony, "Ethicon's attempts to develop lighter weight, large pore meshes and the multiple reasons for doing so") (incorporated by reference). After surveying the relevant literature, Dr. Klinge concludes that "the greater the surface area of a medical implant, the greater the foreign body reaction and the inflammatory

response will be,” and that “the smaller the distance between the fibers of a mesh implant, the greater the risk of scar tissue forming in the pores.” *Id.* at 2, 3.

This Court has repeatedly determined that Dr. Klinge is qualified to testify on these subjects, and that his bases for doing so are reliable. *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, 2014 WL 186782 (S.D. W. Va. Jan. 15, 2014); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 (S.D. W. Va. Aug. 24, 2016). Inasmuch as Ethicon objects to Dr. Klinge’s testimony because he has some reservations about the use of Ultrapro or that he would not want polypropylene mesh, including Ultrapro, in *his* body, if determined relevant, those issues are fodder for cross-examination, not grounds for exclusion. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at 10 (S.D. W. Va. April 24, 2015) (alleged “[c]ontradictions in testimony should be addressed on cross-examination”) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993) (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”)).

Furthermore, as this Court has ruled previously, “[a] single expert need not provide all the pieces of the puzzle for their testimony to be useful to the jury in determining the ultimate issues in the case.” *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 (S.D. W. Va. Aug. 24, 2016). Dr. Klinge has thoroughly explained why a lighter-weight, larger-pore mesh like Ultrapro reduces the risk of certain injuries as compared to Prolene and has provided abundant scientific data to support his opinions. That is, at most, all that is required.

3. PVDF

Also rejected in the Wave One *Daubert* challenges was Ethicon’s rehashing of its argument that Dr. Klinge’s testimony concerning safer alternative synthetic mesh made of PVDF is

speculative. For the same reasons, the Court should again deny Ethicon's motion on this well-worn topic.

In response to the first round of briefing on this topic, this Court issued a well-reasoned *Daubert* opinion finding the challenged opinion to be proper. *In re Ethicon*, 2014 WL 186782, at *6-7. Despite this, Ethicon rehashes many of the same arguments again that have already been appropriately rejected by this Court. As this Court previously held, "[I]n his expert report, Dr. Klinge cites several academic articles and studies for the proposition that PVDF does not degrade like polypropylene and that PVDF meshes show little signs of surface cracking, inflammation, or scar formation after implantation." *Id.* The Court then listed some of the PVDF publications referenced by Dr. Klinge in his *Lewis* report, all of which are cited in the same form in Dr. Klinge's expert reports prepared for these Wave 3 cases. Specifically, Dr. Klinge bases his opinion that PVDF is a superior alternative to polypropylene on the same studies the Court cited as a reliable basis in *Lewis*. Ex. 2, at 37 (citing Klink, et al., Silva, et al., Conze, et al., Klinge, et al, Otto, et al. and Laroche, et al.) Dr. Klinge also cites Ethicon's own scientists for the proposition that PVDF "has a reduced foreign body reaction compared to Prolene . . . and will improve the perceived biocompatibility of our mesh." *Id.* at 37.⁷ Yet Ethicon does not even attempt to distinguish this Court's decision in *Lewis*. Nor does it attempt to distinguish this Court's recent decision in *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 (S.D. W. Va. Aug. 24, 2016). Instead, Ethicon argues that Dr. Klinge's testimony regarding PVDF is unreliable simply because there is only one company that makes an SUI sling out of this material

⁷ Plaintiffs are mindful of the Court's admonitions in its recent (and previous) rulings regarding the introduction of corporate evidence through expert witnesses. However, as the Court has stated, "[a]n expert may testify about his review of internal corporate documents solely for the purpose of explaining the basis for his or her expert opinions – assuming the expert opinions are otherwise admissible." The use of Ethicon's internal documents here regarding their test results showing that PVDF had less foreign body reaction compared to the Prolene used in the TVT products is used precisely for the purpose of further explaining the basis of Dr. Klinge's opinions (as well as his own published opinions in this regard) that PVDF is a feasible alternative design to that of Prolene.

and because he consults with the company that makes the product. Def.'s Brf. at 7. Ethicon then simply cherry-picks a few statements in Dr. Klinge's testimony, suggesting that those handful of sentences refute the wealth of information provided in Dr. Klinge's report.

As explained by Dr. Klinge, beginning in 1998, while he was a consultant to Ethicon, the company studied the efficacy of PVDF and in fact received 510(k) clearance in 2000 for a PVDF suture (Klinge report attached as Exhibit 2, at 26-28). Following a number of internal Ethicon studies revealing that PVDF mesh improved biocompatibility, had fewer quality issues, and had less breakage when compared to Prolene, Ethicon determined that PVDF mesh was the "holy grail" of pelvic floor meshes. *Id.* at 28. Ethicon's sole basis for refusing to seek FDA clearance for the PVDF devices was expense-related. *Id.* Thus, PVDF mesh was clearly available to Ethicon as an alternative to Prolene devices – and as such, it was most certainly feasible. In fact, other mesh manufacturers have received 510k clearance to market PVDF mesh products that are currently being sold in the United States for hernia repairs demonstrating that it was feasible for Ethicon to have brought a PVDF mesh for POP or SUI to the market, but simply chose not to. (*See FDA 510(k) number K131530, dated October 23, 2013, approving Dynamesh PVDF mesh for sale in the U.S.* attached as Exhibit 10.

In accordance with such reasoning, this Court previously ruled against BSC on the same type of argument Ethicon lodges here:

BSC next argues that Ms. Winebarger cannot offer substantial evidence that BSC failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design. Ms. Winebarger, however, offers evidence suggesting that a different mesh prototype was offered to BSC two years before Ms. Winebarger's surgery. (Resp. Mem. in Supp. [Docket 59], at 10-11 (citing Letter from Peter H. Gingras, Managing Partner, Proxy Biomedical Ltd., to James Goddard, BSC (Oct. 24, 2008) [Docket 59-18])). Furthermore, Ms. Winebarger demonstrates that BSC was cognizant of the benefits of a lighter mesh, (Resp. Mem. in Supp. [Docket 59], at 11 (citing Memo from Jim Goddard to Al Intoccia, et al. (Nov. 25, 2008) [Docket 59-4])), including the expectation that "less mesh leads to less inflammation which leads to better outcomes (less dyspareunia, less erosions, less PP degradation over

time).” (Resp. Mem. in Supp. [Docket 59], at 11 (citing E-mail from John Sherry to Abby Fischer, et al. (May 29, 2009, 1:17 AM) [Docket 59-10])). Accordingly, a reasonable juror could determine that BSC failed to adopt a reasonable alternative design.

In re Boston Scientific Corp., No. 2:13-cv-28892, 2015 WL 1509380, at *6 (S.D. W. Va. April 1, 2015); *see also Sanchez*, 997 S.W.2d at 592 (“qualified expert testimony on the issue [of alternative designs] suffices, even though the expert has produced no prototype, if it reasonably supports the conclusion that a reasonable alternative design could have been practically adopted at the time of sale”) (quoting RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 cmt. f (1998)). As demonstrated above, Dr. Klinge’s report details the same type of evidence with respect to Ethicon’s consideration of PVDF that the Plaintiff put forth in her case against Boston Scientific. Dr. Klinge should be permitted to offer his opinion that Ethicon could have implemented PVDF in its pelvic floor products.

In its recent *Daubert* opinion, this Court stated as follows: “Ethicon challenges the reliability of Dr. Klinge’s expert testimony about polyvinylidene fluoride (“PVDF”) mesh. As I have found before, this expert testimony is reliable.” *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 at *5-6 (S.D. W. Va. Aug. 24, 2016) (citing *In re Ethicon Inc.*, No. 2:12-md-2327, 2014 WL 186872, at *7 (S.D. W. Va. Jan. 15, 2014)). The same conclusion remains true today, and Ethicon’s latest motion to exclude Dr. Klinge’s opinions regarding PVDF must again be denied.

B. Dr. Klinge’s Opinions On Alternatives to the Prolene Soft Mesh Used in Ethicon’s Prolapse Products

1. Alternative Design

Plaintiffs incorporate herein by reference all of its briefing above in Section III.A.3. regarding PVDF. However, Ethicon has put two semantic spins on their recycled argument to exclude Dr. Klinge’s opinions regarding PVDF as an alternative to the Gynemesh PS in its Prolift

meshes and thus, plaintiffs will address each one.

First, Ethicon misrepresents to this Court that “Dr. Klinge cites no literature or other reliable, objective data to support” his opinion that PVDF (Dynamesh) is a feasible alternative to the Gynemesh PS used in the Prolift devices. Def.’s Brf. at 8. Nothing could be further from the truth. As stated *supra*, Dr. Klinge references numerous peer-reviewed articles that support his opinions regarding PVDF as an alternative design to Gynemesh PS. (Conze, J., Junge, K., Weiss, C., Anurov, M., Oettinger, A., Klinge, E., Schumpelick, V. *New Polymer for Intra-Abdominal Meshes – PVDF Copolymer*. Journal of Biomedical Materials Research Part B: Applies Biomaterials 2006, attached as Exhibit 3; Klinge et al. *PVDF as a new polymer for the construction of surgical meshes*. Biomaterials 23 (2002) 3487-3493, attached as Exhibit 8).

Additionally, as he does with his SUI Wave expert reports, for his POP Wave expert reports Dr. Klinge incorporates by reference his *de bene esse* testimony regarding Prolift and the Gynemesh PS mesh. In that trial testimony, when discussing an Ethicon- sponsored study, Dr. Klinge states: “...this study clearly confirms that the tissue reaction to the PVDF is better than the polypropylene.” (Klinge *de bene esse* 11/10/14, incorporated as reference to Klinge report, at Exhibit C, 195:5-196:2, attached hereto as Exhibit 2). He also states: “Polypropylene in general produces more inflammation, more scarring than PVDF”. (Klinge *de bene esse* 11/10/14, incorporated as reference to Klinge report, at Exhibit C, 201:14-15, attached hereto as Exhibit 2). The fact that Ethicon chose not to acknowledge these critical scientific references and trial testimony does not negate their existence.

Again, Ethicon does not attempt to distinguish this Court’s recent decision *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 (S.D. W. Va. Aug. 24, 2016). Instead, Ethicon relies on the Court’s *Daubert* opinion in the *Bellew* case where Dr. Klinge had in fact failed to cite to peer-reviewed studies or literature regarding PVDF in that one

report. The Court pointed out that in his *Lewis* report, Dr. Klinge had cited to the Klink and Silva studies (*See* 2014 WL 186872, at *7) whereas in his *Bellew* report, Dr. Klinge failed to do so.

However, Ethicon fails to point out that, in his current Wave 4 reports, as in his *Lewis* report, Dr. Klinge cites numerous peer-reviewed articles, as stated above (*e.g.*, Klink, Conze, Klinge, Otto and Laroche), to support his opinions regarding PVDF as an alternative to Prolene. Thus, Ethicon's argument is factually incorrect, at best. And its assertion that "[i]n short, nowhere in his Rule 26 expert report or in his *de bene esse* deposition does Dr. Klinge cite any peer-reviewed literature that demonstrates that PVDF or a mesh with larger pores would actually be safer alternatives to Prolene Soft" is patently false. Def.'s Brf. at 10. Dr. Klinge's testimony that PVDF(and/or meshes with less weight and larger distance between the fibers) are alternatives to both Ethicon's SUI and POP meshes is relevant, reliable and permissible under *Daubert* scrutiny.

2. Fraying/Particle Loss

In its recent Wave One *Daubert* opinion, this Court reserved ruling on Ethicon's motion to exclude Dr. Klinge's opinions regarding fraying and particle loss of the POP product, Prolift, based at least in part on Ethicon's arguments in its briefing that Dr. Klinge relied primarily on SUI studies rather than POP products and that Prolene Soft has a different weight and pore size "that might affect this analysis." *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liability Litig.*, No. 2:12-MD-02327, Dkt. 2642 at *7 (S.D. W. Va. Aug. 24, 2016). Picking up on the Court's language in its order, Ethicon again moves the Court to exclude Dr. Klinge's testimony in this regard, essentially on the exact same grounds. But Ethicon's arguments are without merit and should not be entertained by this Court.

First, the articles cited by Dr. Klinge regarding the propensity of the edges of Ethicon's TVT meshes to fray and lose particles are based upon the exact same cutting of the TVT textile as the Prolift textile during the manufacturing process – without sealed borders, *any* mesh, or any

textile for that matter will fray and lose particles. (Klinge Expert Report attached as Exhibit 2, at 11, 19-20, 23). This, as stated by Dr. Klinge, is a basic concept of textile manufacturing that is completely analogous to meshes and specifically, Ethicon's TVT and Prolift meshes. *Id.* These mesh studies and internal documents cited by Dr. Klinge showing the fraying and particle loss of TVT meshes were before Ethicon decided to manufacture the Prolift device. As such, Ethicon was aware of this design flaw before they ever sold the Prolift device; namely, that meshes that have cut edges without sealed borders tend to fray at the edges and ultimately, to lose particles into the surrounding tissue.

But Dr. Klinge does not stop there – and neither did other scientists who studied the Gynemesh PS mesh utilized in Ethicon's Prolift mesh. Dr. Klinge and other scientists studied the Gynemesh PS and published it in the peer-reviewed scientific literature and referenced it in his report. (Otto, J., Kirschner-Hermanns, R., Muhl, T., Klinge, U. *Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates*. J Biomed Mater Res Part A 2013:00 000-000; Klinge Expert Report attached as Exhibit 2, at 14). For example, one exhibit used during Dr. Klinge's trial testimony regarding the propensity of Prolift to fray, curl, rope and lose particles is attached to this response as Exhibit 9. In this exhibit, Dr. Klinge shows an internal Ethicon study showing the Prolift mesh fraying; a Prolift implantation video done by an Ethicon preceptor surgeon demonstrating fraying; and Dr. Klinge's own peer-reviewed study showing the Prolift mesh fraying. When discussing Dr. Muehl's testing of the pelvic floor products, it is noted that:

Yet another significant observation during the porosity testing by Prof. Muehl was the 'fraying' at the edges of mesh which could be seen upon removal from the package but became markedly worse in the Prolift mesh sample at minimal strain. These frayed edges create an increased inflammatory process. When frayed edges occur in the curled arms, an even greater inflammatory process is created. After being subjected to even minimal strain or tension, the arms in the Prolift not only curled, frayed and demonstrated deformation of the pores, they also failed to return to their original or near-original geometric shape and

design. This phenomenon is known in material science as plastic deformation.

(Klinge report, attached as Exhibit 2 at 15). In short, despite Ethicon's contentions, Dr. Klinge has provided a "reasonable basis to support his opinion that fraying and particle loss occur" and has explained "the clinical significance...of fraying and particle loss" (Def's Brf. at 11); namely: increased inflammation and foreign body response.

IV. Conclusion

Based on the foregoing, plaintiffs respectfully request that this Court deny Ethicon's motion in its entirety or at a minimum the plaintiffs request that ruling be reserved until trial.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2017, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace